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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,609	07/25/2003	Etsuko Matsunaga	240944US0	9357

22850 7590 12/17/2004

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EXAMINER

HELMER, GEORGIA L

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 12/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/626,609	<b>Applicant(s)</b> MATSUNAGA ET AL.	
	<b>Examiner</b> Georgia L. Helmer	<b>Art Unit</b> 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/18/03</u> . | 6) <input type="checkbox"/> Other: ____.  |

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 1-5 are pending and examined in the current Office Action.

### ***Information Disclosure Statement***

2. The Office acknowledges receipt of Applicant's Information Disclosure Statement (PTO-1449), filed 18 December 2003. A signed copy of Applicant's Information Disclosure Statement is enclosed

### ***Claim Rejections - 35 USC § 112 second paragraph***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. All dependent claims are also rejected

In claim 1, line 3,

- "gene" is unclear because a "gene" implies a DNA sequence that exists in nature and includes coding and noncoding regions, as well as all regulatory sequences associated with expression. Since this does not appear to be Applicant's intention, the language "a DNA of interest" is suggested. Or Applicant may recite the various

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components of the "gene" desired. All recitations of "gene" are also rejected.

In claim 1-3, "an auxin precursor and/or an analogue thereof" is unclear.

What does this mean?

In line 9, "an auxin precursor"—is confusing because line 7 recites " an auxin precursor". Is the one in line 9 the same or a different, auxin precursor?

In line 10, "redifferentiated" is confusing because no undifferentiated tissue is set forth.

Claims 1-4 are rejected as improper methods claims, since the desired product, namely a transgenic plant, are not produced by the final step of the method.

Correction/clarification is required.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

6. Claims 1-4 are rejected under 35 U.S.C. 102(a) as being anticipated by Endo et al. (A new GST-MAT vector containing both isopentenyl transferase and *iaaM/iaaH* can produce marker-free transgenic tobacco plants with high frequency, Plant Cell Reports, 2002, Vol. 20, pages 923-928) IDS.

Endo et. al. teach a method for producing a transgenic tobacco plant comprising (a) introducing a vector in a plant cell, wherein the vector is for gene introduction in a plant, comprising a desired gene and a selectable marker gene comprising a gene encoding an enzyme which synthesizes auxin from an auxin precursor, wherein the gene is *iaaH* (p. 925, 1<sup>st</sup> ¶ ) (b) culturing the plant cell into which the genes are introduced in the presence of an auxin precursor and/or analogue, wherein the auxin precursor is indoleacetamide (p. 924, 1<sup>st</sup> column, 1<sup>st</sup> ¶ , final 10 lines) (claim 2), to prepare a redifferentiated tissue (p.925, 2<sup>nd</sup> full ¶ ) , and detecting and selecting the redifferentiated tissues, and (c) culturing the redifferentiated tissue selected in (b) to redifferentiate into a plant (p. 927, 1<sup>st</sup> ¶ , final sentence ).

The *iaaM* gene catalyzes the production of tryptophan to indoleacetamide. This indoleacetamide is the substrate for the *iaaH* gene which catalyzes the production of indole acetic acid (IAA) (p. 924, 1<sup>st</sup> column, 1<sup>st</sup> ¶ , final 10 lines). The redifferentiated tissue (p.925, 2<sup>nd</sup> full ¶ ) prepared is the shoots which are produced from the callus.

Endo et. al. also teach the method wherein the selectable marker gene comprising a gene encoding the auxin synthesis gene further comprises the cytokinin synthesis gene, isopentenyl transferase (p. 924, column 1, 1<sup>st</sup> ¶ lines 1-9)(claim 4).

Accordingly, Endo et. al. anticipates the claimed invention.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Endo et al. (A new GST-MAT vector containing both isopentenyl transferase and *iaaM/iaaH* can produce marker-free transgenic tobacco) as discussed above for claims 1-4.

The teachings of Endo et. al. are discussed above as they relate to claims 1-4.

Endo et. al. do not teach a vector comprising a selectable marker gene comprising an *iaaH* gene and isopentenyl transferase gene and lacking the *iaaM* gene (claim 5).

Endo et. al. teach a vector comprising a selectable marker gene comprising an *iaaH* gene and isopentenyl transferase gene and the *iaaM* gene.

It would have well within the means of one skilled in the art to delete the *iaaM* gene from the vector of Endo et. al. , to produce the vector comprising *iaaH* and isopentenyl transferase genes, and lacking the *iaaM* gene.

Thus the claimed invention would have been prima facie obvious as a whole to one of ordinary skill in the art at the time it was made, especially in the

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absence of evidence to the contrary. Accordingly, the claimed invention is prima facie obvious in view of the prior art.

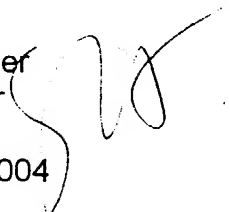
**Remarks**

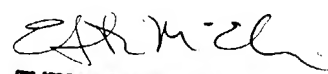
9. No claims are allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 571-272-0976. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Georgia L. Helmer  
Patent Examiner  
Art Unit 1638  
December 13, 2004



  
ELIZABETH MCELWAIN  
PRIMARY EXAMINER